Bensulide Technical Briefing

June 16, 1999

Introduction and Background Information

Introduction

Purpose of Briefing

- Review risk assessment for Bensulide
- Begin public participation period on risk mitigation strategies

Introduction

Bensulide Risk Assessments Consider:

- Dietary risk
  - food, drinking water
- Worker risk
  - handlers, applicators, and workers reentering treated turf
- Residential
  - adults and children entering treated areas (golf courses, home lawns)
- Aggregate
  - food, drinking water, residential
- Ecological risks
  - birds, mammals, fish, and aquatic species

Introduction

TRAC Pilot Public Participation Process for Bensulide

Phase	Health Effects Assessment	Ecological Assessment
❶ "Error Only" Review	N/A	N/A
❷ Public Docket Opened	8/98	8/98
❸ Comment Period Completed	10/98	10/98
❹ Revised Assessment Sent to USDA	2/99	2/99
❺ Solicit Risk Management Options	6/16/99	6/16/99
❻ Develop Risk Management Strategy		

Introduction

- **Phase 1: Not Applicable**

- **Phase 2: Open Public Docket**
  - 60-day public comment period.

Introduction

Phase 3: Public Comment

- Comments received from registrant, public interest groups, growers, USDA
- Registrant concerned about:
  - dermal absorption value used
  - intermediate-term exposure assessment for handlers
  - assumptions used in occupational and residential risk assessments
- Weed Scientist provided information on use in southwestern U.S.
- Generic comments on science and policy

Introduction

New Data Received

- 21-Day Dermal Toxicity Study
- Aquatic Toxicity Study
- ORETF Turf Transferable Residue (TTR) Study

Introduction

Phase 4: Revise Assessments, Solicit Comments from USDA

- Refinement of dietary assessment (DEEM)
- Revisions to worker & residential risk assessment include:
  - use of dermal toxicity study (dermal absorption factor not applied)
  - use of Occupational & Residential Exposure Task Force (ORETF) data
- Revisions to ecological assessment
  - use of ORETF data to confirm risk assessment; revised risk characterizations

Regulatory History

- First registered in 1964 for pre-emergence control of crabgrass and annual bluegrass on turf
- Registered for weed control in food crops in 1968

Use Profile

- Currently Registered Uses
  - About 20 food uses (including minor crops)
  - Used on turf (lawns, golf courses)
- Sources of Use Data
  - Registrant
  - USDA
  - National Center for Food and Agriculture Policy

Use Profile

Usage

- 500,000 pounds used per year (on average)
  - About 70% on food
  - About 30% on turf (mainly golf courses)

High-Use Food Crops

- > 20% crop treated for cantaloupes, squash, and melons
- > 10% crop treated for honeydew, onions, and pumpkins
- < 2% crop treated for golf courses
- < 1% crop treated for lawn care by professional operators
- small unknown usage by homeowners

Use Profile

Major Use Regions

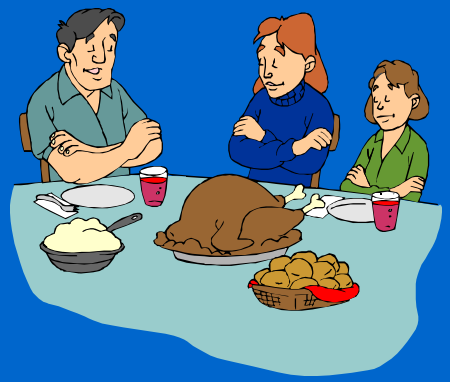
- California, Arizona and Texas for food crops
- East coast, southern and northern U.S. regions for turf use

Use Profile

Use Practices

- Application Methods
- Use Rates
  - number of applications
  - pounds per acre
- Reentry Intervals
  - Agricultural Sites
    - 12 hours on labels
  - Turf Sites
    - None on current labels

Human Health Risk Assessment



www.epa.gov/pesticides/op/Bensulide.htm

Risk Assessment Components

- Dietary
  - Food
  - Drinking Water
- Occupational
  - Handlers/Applicators
  - Workers (post-application)
- Residential
  - Home
  - Golf Courses
- Aggregate (food, drinking water, residential)

Dietary Risk Equation

Risk = Hazard x Exposure, where

Exposure = Consumption x Residue

Dietary Risk Assessments

Acute

- Risk assessment reflecting one-day dietary exposures to pesticide residues

Chronic

- Risk assessment reflecting lifetime (long-term) exposures to pesticide residues

Effect Levels

- Lowest Observed Adverse Effect Level = LOAEL
  - Is the lowest dose at which an “adverse” health effect is seen. Has units of mg per kg body weight per day.
- No Observed Adverse Effect Level = NOAEL
  - Is the dose at which no “adverse” health effect is seen. This dose is less than the LOAEL. Has units of mg per kg body weight per day.

Acute Hazard (toxicity)

- **Study**: Rat acute neurotoxicity study showed plasma cholinesterase inhibition
- **Endpoint**: Cholinesterase inhibition
  - **NOAEL**: 15 mg/kgBW/day
- *Endpoints from this study most accurately reflect toxicity which could result from one-day dietary exposure to Bensulide*

Chronic Hazard (toxicity)

- **Study**: 1-year chronic toxicity study in dogs showed brain and plasma cholinesterase inhibition; decreased body weight gain
- **Endpoint**: Cholinesterase Inhibition
  - **NOAEL**: 0.5 mg/kgBW/day
- *Endpoints from this study most accurately reflect toxicity which could result from long-term dietary exposure to Bensulide.*

Uncertainty Factors

- 10X — Interspecies Variability
- 10X — Intraspecies Sensitivity
- 1X — FQPA Safety Factor Removed
- 100X — Total UF for all Human Health Risk Assessments

This would have been a typical type of uncertainty analysis, even before FQPA.

Analysis of Special Sensitivity of Infants and Children

- No developmental effects in fetuses below maternally toxic doses.
- No increased sensitivity in pups relative to adults.
- No abnormalities in developing fetal nervous system.
- No histopathology of the nervous system.
- Complete toxicity database.
- Good data -- unlikely that exposures are underestimated.

Reference Doses for Bensulide

$$\frac{\text{NOAEL}}{\text{UF}} = \text{acute RfD} = 0.15 \text{ mg/kg BW/day}$$

$$\frac{\text{NOAEL}}{\text{UF}} = \text{chronic RfD} = 0.005 \text{ mg/kg BW/day}$$

$$\%\text{RfD} = \frac{\text{Exposure}}{\text{RfD}} \times 100$$

Expression of Risk for Bensulide

- Dietary Exposure

$$\%RfD = \frac{\text{Exposure}}{\text{RfD}} \times 100$$

  - Less than 100% RfD is protective
  - Small # indicates safety

- Non-dietary Exposure

$$MOE = \frac{\text{NOAEL}}{\text{Exposure}}$$

  - An MOE of 100 or greater is protective
  - Large # indicates safety

Dietary Exposure

- All tolerances are based on non-detectable residues
- No detects in field trials or monitoring
- No Monte-Carlo analysis

Acute Dietary Analysis Results

Risk Estimates as a Percentage of the Acute RfD

Population	% aRfD
General U.S.	0.04%
Infants < 1 year	0.05%
Non-nursing Infants	0.05%
Children 1-6	0.08%
Children 7-12	0.05%

Assessment was done using DEEM (the Dietary Exposure Evaluation Model).

Chronic Dietary Analysis Results

Risk Estimates as a Percentage of the cRfD

Population	% cRfD
General U.S.	0.3%
Infants < 1 year	0.6%
Non-nursing Infants	0.8%
Children 1-6	0.4%
Children 7-12	0.3%

Assessment was done using DEEM (the Dietary Exposure Evaluation Model).

Drinking Water Risk Assessment

- Assessment conducted because of Bensulide's use pattern and environmental fate profile.
  - Highly persistent
- Environmental fate data indicate Bensulide can get into surface water and ground water to some extent.
- No monitoring data were available, so a drinking water assessment based on modeling was conducted.

Drinking Water Risk Assessment

- Determined exposure to Bensulide in food first, then considered any remaining allowable exposure in drinking water.
- Example:
  - For the U.S. population, 0.3% of the chronic RfD used by exposure through food
  - 99.7% of the chronic RfD remaining for exposure through drinking water

Drinking Water Risk Assessment

Acute

- Drinking water exposure based on model estimates did not exceed the amount of the acute RfD allocated for ground & surface water.
  - Conclude: acute exposure to Bensulide in drinking water not a concern.

Drinking Water Risk Assessment

Chronic

- Drinking water exposure based on model estimates exceeds the amount of the chronic RfD allocated for surface water.
  - Conclude: screening indicates chronic exposure to Bensulide in drinking water may be of concern.
  - Concerns are driven by turf use (i.e., golf courses).
  - Modeling assumes treatment of entire golf course; use of highest label rate

- Monitoring Data May Refine Risk Assessment

Drinking Water Risk Assessment

- Screening-level assessment considered health-protective because drinking water exposures are based on conservative model estimates.

Occupational & Residential Risk Assessments

Incorporated New Studies:

- 21-day Dermal Toxicity
- Turf Transferable Residue (TTR)
  - submitted as part of ORETF Data Call-In

Occupational & Residential Risk Assessments

- Short-term and Intermediate-term dermal endpoint: 50.0 mg/kg/day
- Short-term inhalation endpoint: 5.5 mg/kg/day
- Intermediate-term inhalation endpoint: 0.5 mg/kg/day
- Short-term exposure = 1 to 7 days
- Intermediate-term exposure = more than 7 days

Occupational Risk Assessments Conducted

Handlers

- professional agriculture applicators
- lawncare and turf management professionals
- farmer/growers who mix, load and apply pesticides

Post-Application Workers

- includes workers performing turf management activities

Occupational Assessment

Factors Forming the Basis for Handler Risk Assessment

- Formulation and application equipment (e.g., wettable powder, groundboom)
- Levels of protection
- Rate of application (lb ai/acre)
- Areas treated per day (e.g., acres/day)
- Toxicity endpoint (mg/kg/day)

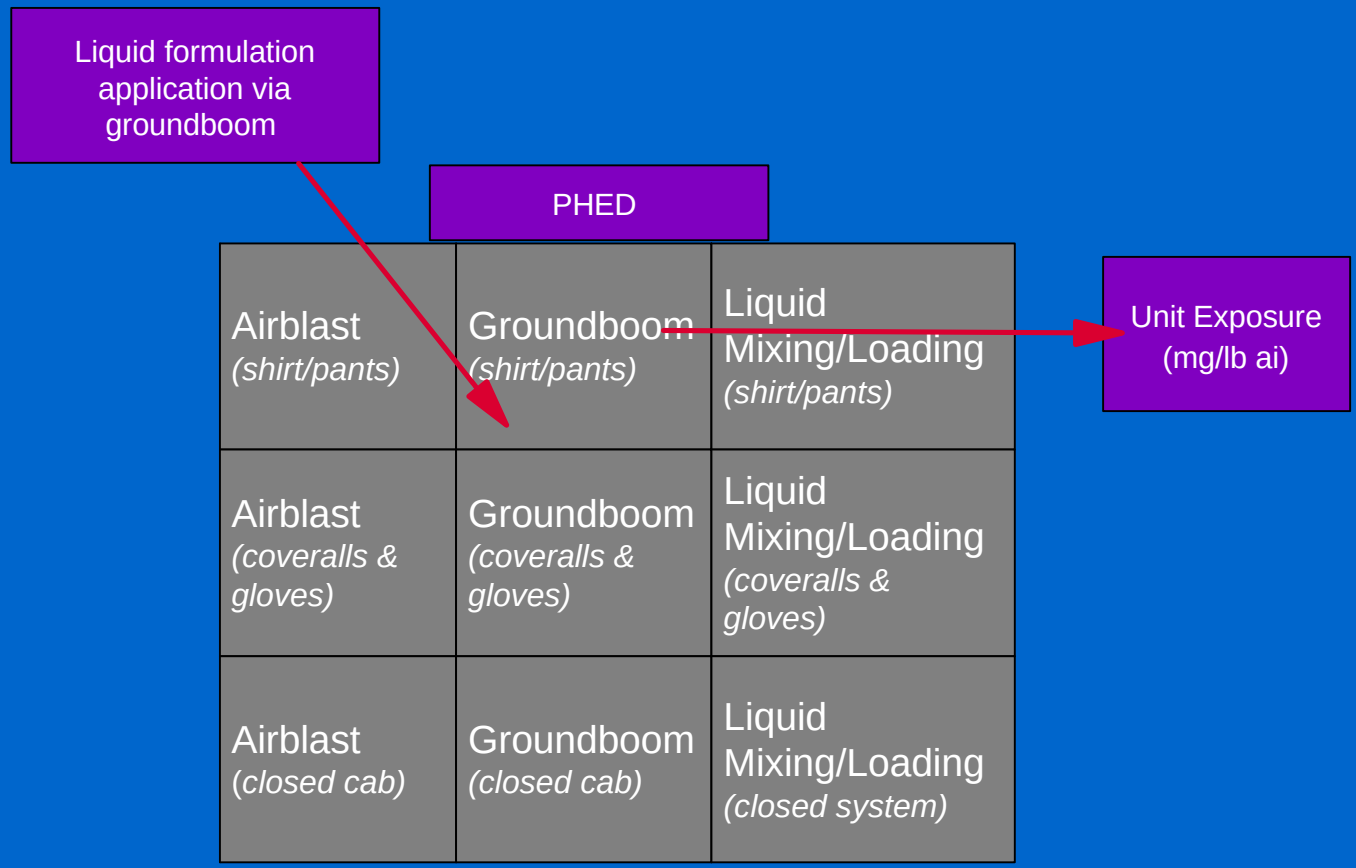
Occupational Assessment

Handler Risk Calculation

$$\text{Dose} = \frac{(\text{unit exposure}) \times (\text{appl. rate}) \times (\text{acres/day})}{\text{Body Weight (70 kg)}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

Occupational Assessment



Occupational Assessment

Handler Scenarios: Agricultural

- (1a) M/L* Liquids for Chemigation
- (1b) M/L Liquids for Groundboom
- (3) Applying Sprays for Groundboom

*Mixer/Loader

Occupational Assessment

Handler Scenarios: Golf Courses

- (1b) M/L Liquids for Groundboom
- (2) Loading Granules for Tractor-drawn Spreader Application
- (3) Applying Sprays w/ Groundboom
- (4) Applying Granules w/ Tractor-drawn Spreader
- (5) M/L/A Low Pressure Handwand
- (6) M/L/A High Pressure Handwand
- (7) M/L/A Backpack Sprayer
- (8) M/L/A Low Pressure/High Volume Turfgun

*Mixer/Loader/Applicator

Occupational Assessment

Handler Scenarios: Lawncare (Professional)

- (1c) M/L Liquids for Professional Turf Application
- (5) M/L/A Low Pressure Handwand
- (6) M/L/A High Pressure Handwand
- (7) M/L/A Backpack Sprayer
- (8) M/L/A Low Pressure/High Volume Turfgun
- (9) M/L/A Push Type Granular Spreader
- (10) M/L/A Belly Grinder

Occupational Assessment

Bensulide Labels Require:

- Long Pants
- Long-sleeved Shirt
- Chemical Resistant Gloves

Occupational Assessment

Handler Results: Agricultural

- Based on current labels, only one scenario, high-acreage chemigation, is of concern for dermal exposure
- Some scenarios are of concern for intermediate-term inhalation exposure

Occupational Assessment

Handler Results: Golf Courses

- Based on current labels, only two scenarios are of concern for dermal exposure:
  - (6) M/L/A High Pressure Handwand
  - (7) M/L/A Backpack Sprayer

- Most scenarios are of concern for intermediate-term inhalation exposure

Occupational Assessment

Handler Results: Lawncare (Professional)

- Based on current labels, four scenarios are of concern for dermal exposure:
  - (6) M/L/A High Pressure Handwand
  - (7) M/L/A Backpack Sprayer
  - (9) M/L/A Push Type Granular Spreader
  - (10) M/L/A Belly Grinder

- Most scenarios are of concern for intermediate-term inhalation exposure

Occupational Assessment

Post-Application Scenarios

- Turf
- Agricultural

Occupational Assessment

Factors Forming the Basis for Post-Application Worker Risk

- Turf Transferable Residues (TTR):
  - amount of residue that workers could contact in field.
- Transfer Coefficient (TC):
  - indicator of amount that workers actually contact during various field activities.

Post-Application Worker Risk Calculation

$$\text{Dose} = \frac{\text{TTR } (\mu\text{g/cm2}) \times \text{TC (cm2/hour)} \times \text{hours}}{\text{Body Weight (kg)}}$$

Occupational Assessment

Sources of Information

TTR Data:

- Turf data submitted by registrant under a large Data Call-In (DCI) issued by the Agency in 1995.

Transfer Coefficients:

- Chosen to represent low and high exposure activities

Occupational Assessment

Post Application Risk Assessment Results

- Turf: MOEs >100 even on day of application - current label is protective.
- Agricultural: Generally no concerns because of use pattern (i.e., pre-plant/pre-emergent herbicide).

Bensulide Incident Reports

Sources

- OPP Incident Data System
- Poison Control Centers, 1993-1996
- California Department of Pesticide Regulation
- National Pesticide Telecommunication Network

Conclude: Relatively few illness cases have been reported due to bensulide.

Residential Risk Assessments Conducted

Handlers

- *includes homeowner applicators treating turf and ornamentals (granular products)*

Post-Application

- *includes exposure to adults and children following applications to turf (including home lawns and golf courses)*

Residential Assessment

Handler Scenarios: Lawncare (Homeowners)

- (9) M/L/A* Push Type Granular Spreader
- (10) M/L/A Bellygrinder

*Mixer/Loader/Applicator

Residential Assessment

Homeowner Labels (granular products)

- Require homeowner to “sprinkle the area with water for 10-15 minutes after application…”*
- Allows use rates of up to 12.5 lbs/a.i. Per application
- Allows application with lawn spreader or bellygrinder

* Registrant study irrigated with ½ inch water immediately after application and used 12.5 lbs/a.i. rate.

Residential Assessment

Handler Results: Lawncare (Homeowner)

- Dermal:
  - MOEs >100 for:
    (9) M/L/A Push Type Granular Spreader
  - MOEs <10 for:
    (10) M/L/A Bellygrinder

- Inhalation not a concern

Residential Assessment

Post-application scenarios

- Adults & children on treated turf

Residential Assessment

Post-Application Risk Assessment Results on Day of Application

For Uses on Residential Lawns

- Adults: MOEs >100
- Children: MOE >100 (combined dermal & oral)

For Uses on Golf Courses

- MOEs >100

Aggregate Risk Assessment

- Combines exposures from:
  - food
  - drinking water
  - residential and other non-occupational (i.e. golfers)
- Both adults and children considered

Aggregate Risk Assessment

Types of Aggregate Risk Assessments Completed for Bensulide

- Acute: Single day exposures
  - (food & water)
- Short-term & Intermediate-term
  - (food, water, & residential)
- Chronic: Long term exposures
  - (food & water)

Aggregate Risk Assessment - Results

- Acute Aggregate - Food & Water Only
  - Food Exposure Not of Concern
  - Drinking Water Exposure Based on Model is Not of Concern
- Conclude: No Concerns for Acute Aggregate Risk

Aggregate Risk Assessment - Results

- Short-term/Intermediate-term
  = Food, Water & Residential
  - Combined margins of exposure for food and residential exposure do not exceed a level of concern. This assumes use of a spreader and watering in.
  - Combined MOEs do exceed level of concern if bellygrinder is used and/or no watering in.
  - Estimated drinking water concentration are not of concern.

Aggregate Risk Assessment - Results

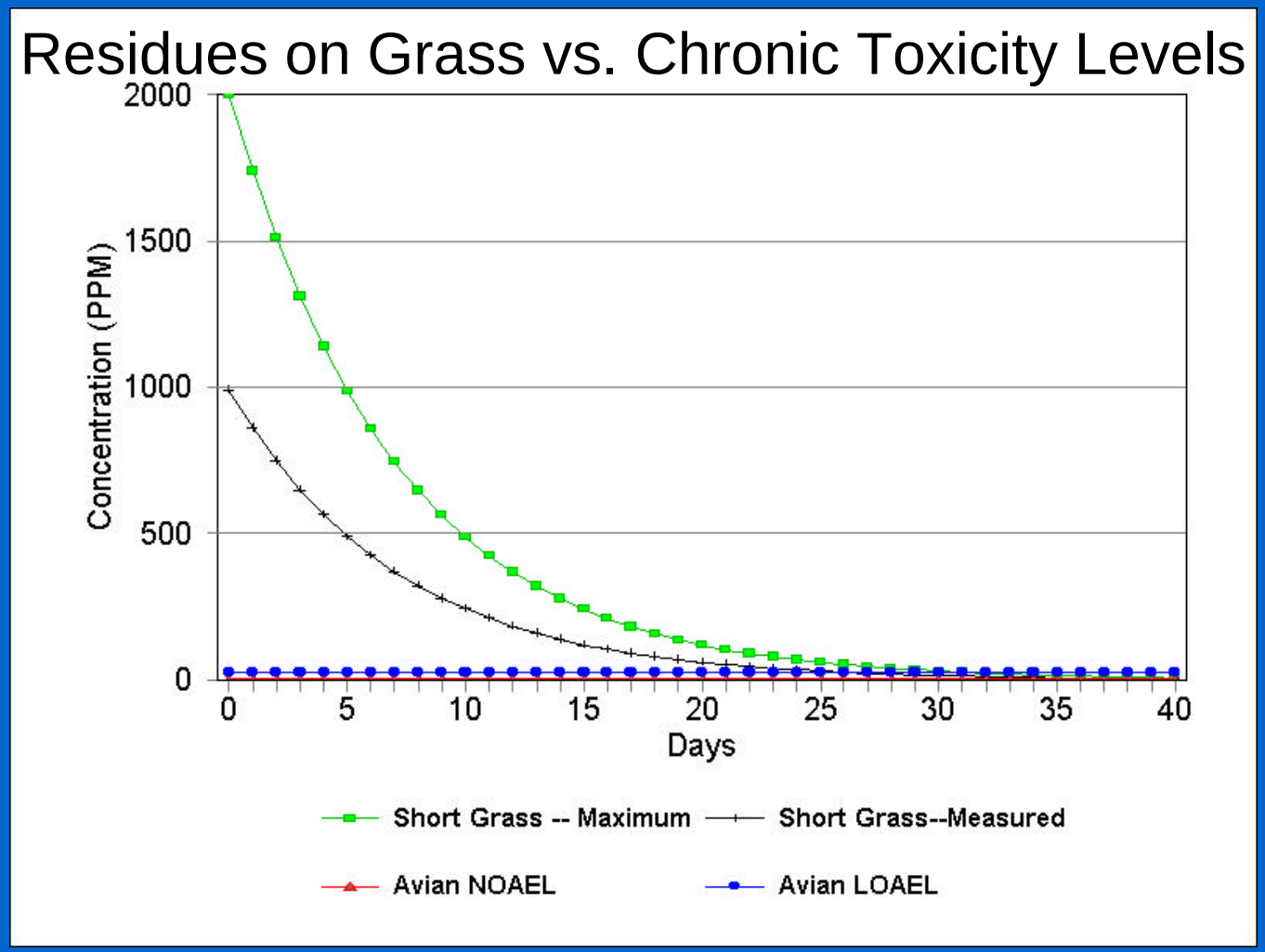
- Chronic Aggregate - Food & Water Only
  - Food Risks Not a Concern
  - Groundwater Drinking Water Exposure Based on Model Estimates is Not of Concern
  - Surface Drinking Water Exposure Based on Model Estimate is of Concern
    - Monitoring Data May Refine Risks

Ecological Risk Assessment

Ecological Risk Assessment

- **Avian**
  - Chronic risk -- eggshell thinning and other reproductive impairments
  - Risks from all uses, but are highest on golf and turf sites.
  - Risk conclusions from preliminary ecological risk assessment were confirmed by Turf Transferable Residue Study.

Chronic Risk to Birds



Ecological Risk Assessment

- Mammals
  - Some acute risk
  - High chronic risk
  - Higher risk from turf use

Ecological Risk Assessment

- Aquatic
  - Primary concern for aquatic invertebrates; minor acute risk to fish
  - Result from surface run-off
  - Surface run-off potential is greatest in turf use areas; potential run-off from vegetable use areas in the desert southwest is lower

Summary and Conclusion

Summary of Acute Dietary Risk Assessment

- Risk from food treated with Bensulide is very **low**.
- When combined with food exposure, drinking water exposure based on modeling may pose chronic risk concerns. Concerns for drinking water exposure associated with turf uses/run-off.

Summary of Remaining Concerns

Risks to Focus on in Phase 5

Agricultural Uses

Handlers

- Dermal exposure concerns for high acreage chemigation
- Inhalation exposure concerns for some scenarios

Golf Courses

- Handlers
  - Concerns for most high exposure application methods (dermal & inhalation)
- Drinking Water
  - Surface water concerns based on modeling
- Ecological
  - Risk to birds, mammals, aquatic invertebrates

Homelawns

- Professional handlers
  - Concerns for most high exposure application methods (dermal & inhalation)
- Homeowner handlers
  - Concern for bellygrinder application method
- Homeowner post-application risk
  - Concern with insufficient watering-in

Phase 5

- Technical Briefing
- Revised risk assessment (incorporating all studies) available in public docket and on the internet
- Begin 60-day public participation period
- Public submits risk management ideas
- Opportunities for growers and others to meet with EPA